1								
2	Department of Commerce, Community and Economic Development Division of Corporations, Business and Professional Licensing							
3	•	ss and Professional Licensing						
4								
5		of Pharmacy						
6								
7		ERGENCY MEETING						
8		1 V: do a conforma						
9 10		1 videoconterence						
11 12 13 14	By authority of AS 08.01.070(2), and in comparticle 6, a scheduled meeting of the Board August 12, 2021. Due to the COVID-19 paneavailable.	of Pharmacy via videoconference on						
16 17	Agenda Item 1 Call to Order/Roll C	Time: 9:30 a.m.						
21 22 23 24 25	Justin Ruffridge, PharmD #PHAP1787 Ashley Schaber, PharmD, #PHAP1697							
26 27	James Henderson, RPh #PHAP1683							
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31	, 1	niner						
32	,	-						
33	, 1	Aanager						
34	Sonia Lipker, Lead Investigator							
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37	<i>.</i>							
38 39 40	Members from the public present/registered:							
+0 41		on						
+1 12	<u> </u>	OII						

43	Caren Robinson, AkPhA
44	Samantha Chessie, Animal Policy Group
45	Reggie Dilliard, Gladstone Consultants, LLC
46	Rep. Ken McCarty, Alaska Legislature
47	Gordon DeVries, Concerned Citizen
48	Renee Stoll, Pharmacy Partners, L.L.C.
49	Olga Brophy, Carrs/Safeway Albertsons Co.
50	Molly Gray, Alaska Pharmacists Association
51	Jessica Adams, TelePharm/Cardinal Health Company
52	Matthew Johnson, State Legislature
53	Christopher Kurka, Office of Representative Christopher Kurka
54	Kevin Mccabe, State House
55	Ursula Chizhik, FLAVORx
56	Kendra Croker, Cardinal Health

Agenda Item 2

Sharon Long

Review/Approve Agenda

Time: 9:31 a.m.

The board reviewed the day 1 meeting agenda. Dr. Ruffridge called for a motion.

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On a motion duly made by Lana Bell to approve the meeting agenda, seconded by Ashley Schaber, and approved unanimously, it was:

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RESOLVED to accept the September 23rd meeting agenda as written.

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67		APPROVE	DENY	ABSTAIN	ABSENT
68	Justin Ruffridge	X			
69	Lana Bell	X			
70	Tammy Lindemuth				X
71	James Henderson	X			
72	Ashley Schaber	X			
73	Leif Holm				X

The motion passed with no further discussion.

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Agenda Item 3 <u>Ethics Disclosures</u>

Time: 9:33 a.m.

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Dr. Schaber disclosed she is involved with the Alaska Pharmacist Association (AKPhA), currently serving as past-present, including board member. Dr. Schaber is also in the chair roll for the By-Laws & Nominations Committee Chair, which will carry through to 2022. Her seat as co-chair will also roll through February 2022. Additionally, Dr. Schaber is a member of the association's Legislative & Convention Committees.

Time: 9:38 a.m.

The board reviewed the May 20-21st and August 12th meeting minutes. Mr. Henderson pointed out errors in the May minutes showing he was absent during some voting periods.

On a motion duly made by Lana Bell to approve the meeting agenda, seconded by James Henderson, and approved unanimously, it was:

RESOLVED to accept the May 20-21st meeting minutes as amended and the August 12th meeting minutes as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson	X			
Ashley Schaber	X			
Leif Holm				X
Sharon Long				X

The motion passed with no further discussion.

TASK 1

Ms. Carrillo will review the minutes for accuracy of Mr. Henderson's voting and will forward the corrected minutes to Dr. Ruffridge for signature.

Agenda Item 5 PDMP Update

Ms. Sherrell presented the PDMP report, including data on registration and recommendations to prescribing boards. Ms. Sherrell stated that enhancement features are expected to be implemented soon, including more data analytics modules and a provider-to-provider communication channel.

Ms. Sherrell informed the board that the reporting compliance process is still a manual, tedious, and complex process. Dr. Ruffridge inquired whether the reporting compliance module would make tracking compliance easier, to which Ms. Sherrell stated it may reduce the number of delinquent reports to assess, but for the most part would be a benefit to the provider.

Dr. Ruffridge inquired about the definition of direct dispenser. Ms. Sherrell clarified direct dispensing applies to prescribers who dispense directly out of their clinic as opposed to picking their prescriptions up at a pharmacy. A pharmacist practicing within a pharmacy would just be considered a dispenser.

129 Case Review Training

Investigator Bowles went through the investigative process workflow. Reviews are performed to 130

determine whether there is a potential violation present, not to determine guilt or innocence. Mr. 131

Bowles proceeded to provide training to the board on their role in the review process.

132 133 134

Investigative Report

Investigator Bowles provided the board its report, which included matters from May 7, 2021 135 136

through September 9, 2021. During this time period, 30 matters closed and 34 remain open.

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Imposition of Civil Fines

The board then addressed imposition of civil fines.

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On a motion duly made by Ashley Schaber in accordance with AS 44.62.310(c)(2), and seconded by Lana Bell, the board unanimously moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.

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RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2). Staff, Michael Bowles, Brenda Smith, Sonia Lipker, Marilyn Zimmerman, and Laura Carrillo were authorized to remain in the room.

148 149

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson	X			
Ashley Schaber	X			
Leif Holm				X
Sharon Long				X

The motion passed with no further discussion.

158 159 160

Off record at 10:27 a.m.

On record at 10:53 a.m. 161

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Upon return from executive session, Chair Ruffridge clarified that no motions were made during executive session. The board first reviewed matters relating to imposition of civil fines. Where applicable, abstention votes indicate the voting board member reviewed the case.

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On a motion duly made by Justin Ruffridge to accept the imposition of civil fine for case #2020-000530 in the amount of \$500.00, and seconded by Lana Bell, it was:

Time: 9:56 a.m.

RESOLVED to accept the imposition of civil fine for #2020-000530.

171		APPROVE	DENY	ABSTAIN	ABSENT
172	Leif Holm				X
173	Ashley Schaber	X			
174	Justin Ruffridge	X			
175	Lana Bell	X			
176	Tammy Lindemuth				X
177	James Henderson			X	
178	Sharon Long				X
179	The motion passed	with no further dis	scussion.		

The motion passed with no further discussion.

> On a motion duly made by Lana Bell to accept the imposition of civil fine for case #2020-001084 in the amount of \$500.00, and seconded by Ashley Schaber, it was:

RESOLVED to accept the imposition of civil fine for #2020-001084.

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	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Ashley Schaber	X			
Justin Ruffridge			X	
Lana Bell	X			
Tammy Lindemuth				X
James Henderson	X			
Sharon Long				X

The motion passed with no further discussion.

On a motion duly made by Lana Bell to accept the imposition of civil fine for case #2021-000100 in the amount of \$500.00, and seconded by Ashley Schaber, it was:

RESOLVED to accept the imposition of civil fine for #2021-000100.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Ashley Schaber	X			
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson			X	

208	Sharon Long	X

209 The motion passed with no further discussion.

210211

On a motion duly made by Lana Bell to accept the imposition of civil fine for case #2021-000110 in the amount of \$200.00, and seconded by Ashley Schaber, it was:

212213214

RESOLVED to accept the imposition of civil fine for #2021-000110.

215216

217218219220221222223

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Ashley Schaber	X			
Justin Ruffridge			X	
Lana Bell	X			
Tammy Lindemuth				X
James Henderson	X			
Sharon Long				X

The motion passed with no further discussion.

224225226

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On a motion duly made by Lana Bell to accept the imposition of civil fine for case #2021-000113 in the amount of \$800, and seconded by Ashley Schaber, it was:

229230

RESOLVED to accept the imposition of civil fine for #2021-000113.

231232

233234235236237238239240

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Ashley Schaber	X			
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson	X			
Sharon Long				X

The motion passed with no further discussion.

On a motion duly made by Lana Bell to accept the imposition of civil fine for case #2021-000232 in the amount of \$250.00, and seconded by Ashley Schaber, it was:

242243244

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RESOLVED to accept the imposition of civil fine for #2021-000232.

245246

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X

248	Ashley Schaber	X		
249	Justin Ruffridge	X		
250	Lana Bell	X		
251	Tammy Lindemuth			X
252	James Henderson		X	
253	Sharon Long			X

The motion passed with no further discussion.

254255256

On a motion duly made by Lana Bell to accept the imposition of civil fine for case #2020-000972 in the amount of \$500.00, and seconded by Ashley Schaber, it was:

257258259

RESOLVED to accept the imposition of civil fine for #2020-000972.

260261

262263264265266267268

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Ashley Schaber	X			
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson			X	
Sharon Long				X

The motion passed with no further discussion.

269270271

On a motion duly made by Lana Bell to accept the imposition of civil fine for case #2020-000973 in the amount of \$2,000.00, and seconded by Ashley Schaber, it was:

273274

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RESOLVED to accept the imposition of civil fine for #2020-000973.

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277278279280281282283

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Ashley Schaber	X			
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson			X	
Sharon Long				X

The motion passed with no further discussion.

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Agenda Item 7 Public Comment #1 Time: 11:16 a.m.

Representative Christopher Kurka:

Rep. Kurka stated there are doctors using their clinical judgment to determine ivermectin is useful for case of COVID-19, adding that if patients are interested and willing to experiment with this medication and the doctors prescribe this judgment, it should be filled. Rep. Kurka stated that ivermectin has received a Nobel Prize for treatment in humans, reiterating prescribers should be able to treat their patients with this, but that there are some pharmacies not filling those prescriptions. Dr. Ruffridge thanked Rep. Kurka for his comment and encouraged the public to review their draft Q and A, which will be discussed later in the meeting. Ms. Carrillo provided the page number, 250, located in the public packet.

Representative Ken McCarty:

Rep. McCarty stated he wants to ensure our state has all the medications necessary to combat COVID. As the representative for Eagle River-Chugiak, he has looked at monoclonal antibodies and ways to get this into communities. Rep. McCarty added he is hearing about patients unable to receive monoclonal antibodies around the state and is now hearing ivermectin can't get into the hands of patients. Rep. McCarty is interested in helping with the supply, stating he is a trustee with the Mental Health Trust along with trustee, John Sturgeon, who was instrumental in delivering PPE all over communities in Alaska by plane. McCarty stated it would be ideal for the same to occur with ivermectin and is happy to help with that effort.

Dr. Ruffridge stated for the public that ivermectin is not a commonly prescribed human drug in the U.S. and that the current supply is well below the current demand. Dr. Ruffridge stated he has dispensed 10 years' worth of this drug in about 10 hours, that it is a difficult drug to stock and any concerns about supply right now is valid. Dr. Ruffridge stated he has not experienced a similar supply issue with monoclonal antibodies, but that as the situation continues to unfold, it may become scarce. Ms. Bell added that the supply is being controlled by the federal government and is based on an allocation. The Alaska Department of Health and Social services is working with the federal government and advocating for supply, though it is ultimately not controlled by the state.

TASK 2

Dr. Ruffridge will submit written responses to Representatives Kurka and McCarty's questions following the meeting.

Agenda Item #6 <u>Investigative Update</u>

11:32 a.m.

Imposition of civil fines

The board returned to the investigative review of imposition of civil fines.

On a motion duly made by Lana Bell to accept the imposition of civil fine for case #2020-000163 in the amount of \$250.00, and seconded by Ashley Schaber, it was:

RESOLVED to accept the imposition of civil fine for #2020-000163.

331		APPROVE	DENY	ABSTAIN	ABSENT
332	Leif Holm				X
333	Ashley Schaber	X			
334	Justin Ruffridge	X			
335	Lana Bell	X			
336	Tammy Lindemuth				X
337	James Henderson	X			
338	Sharon Long				X

The motion passed with no further discussion.

On a motion duly made by Lana Bell to accept the imposition of civil fine for case #2020-000790 in the amount of \$1,000.00 and seconded by Ashley Schaber, it was:

RESOLVED to accept the imposition of civil fine for #2020-000790.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Ashley Schaber	X			
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson			X	
Sharon Long				X

The motion passed with no further discussion.

Voluntary surrender

The board then moved to review matters relating to voluntary surrenders.

On a motion duly made by Justin Ruffridge to accept the voluntary surrender for case #2020-000655, and seconded by James Henderson, it was:

RESOLVED to accept the voluntary surrender for #2020-000655.

364		APPROVE	DENY	ABSTAIN	ABSENT
365	Leif Holm				X
366	Ashley Schaber	X			
367	Justin Ruffridge	X			
368	Lana Bell			X	
369	Tammy Lindemuth				X

370	James Henderson x	
371	Sharon Long	X

The motion passed with no further discussion.

Consent agreement

The board then reviewed a matter related to a continuing education consent agreement.

On a motion duly made by Lana Bell to accept the consent agreement for case #2021-000087, and seconded by James Henderson, it was:

RESOLVED to accept the consent agreement for #2021-000087.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Ashley Schaber	X			
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson	X			
Sharon Long				X

390 The motion passed with no further discussion.

TASK 3

Ms. Carrillo will send the imposition of civil fines, voluntary surrender, and consent agreement to Dr. Ruffridge for signatures and will forward these to Investigator Bowles.

James Henderson called for break.

Off record at 11:35 a.m.

On record at 11:41 a.m.

401 A

Agenda Item #8

Board Business

11:44 a.m.

Application review

The board then moved onto board business, beginning with application review.

On a motion duly made by Lana Bell in accordance with AS 44.62.310(c)(2), and seconded by Ashley Schaber, the board unanimously moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.

RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2). Staff, Michael Bowles and Laura Carrillo were authorized to remain in the room.

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	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson	X			
Ashley Schaber	X			
Leif Holm				X
Sharon Long				X

⁴²² The motion passed with no further discussion.

Off record at 11:46 a.m.

425 On record at 12:28 p.m.

Upon return from executive session, Chair Ruffridge clarified that no motions were made during executive session. Investigator Michael Bowles joined the board in executive session.

On a motion duly made by Lana Bell to table the application for Zachary Brown, inprocess 117445, and seconded by Ashley Schaber, it was:

RESOLVED to table the application for Zachary Brown until the board's November 18-19, 2021 meeting.

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6	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	1			X
8 Ashley Scl	haber x			
9 Justin Ruf	fridge x			
0 Lana Bell	X			
1 Tammy L	indemuth			X
2 James Hei	nderson x			
3 Sharon Lo	ong			X

The motion passed with no further discussion.

447 TASK 4

Ms. Carrillo will inform Mr. Brown of the board's vote to table the discussion during its

November meeting.

Off record at 11:27 a.m.

452 On record at 12:29 p.m.

Lost/Stolen Prescriptions

The board reviewed lost and stolen prescriptions.

Review/Approve 2022 Strategic Plan

Ms. Carrillo informed the board that a new strategy related to military licensing was added to the regulation and enforcement guiding principles as goal #4, which aims to grow the economy while promoting community health and safety. The new military strategy became #4.5, which bumped the legislation advocacy strategy to #4.6. Dr. Schaber pointed out a typo corrected needing to be made from, "arises" to "arise" in strategy #4.6.

On a motion duly made by Lana Bell to approve the board's 2022 Strategic Plan with the revision to strategies #4.5 and #4.6, and seconded by Ashley Schaber, it was:

RESOLVED to approve the 2022 Strategic Plan as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Ashley Schaber	X			
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson	X			
Sharon Long				X

The motion passed with no further discussion.

TASK 5

Ms. Carrillo will correct the grammar mistake in strategy #4.6 and will submit a request to publish the finalized 2022 Strategic Plan to the board's webpage.

Correspondence

Chair Ruffridge summarized the pieces of correspondence included in the packet:

- FDA vaccinations not yet available for ages 5-12, diligently working to ensure safety and efficacy of products in children, but until that time, vital parents interacting with children take appropriate safety measures.
- Declaration to amendment of PREP Act, 9th amendment, providing liability immunity to and expand scope of authority for qualified pharmacy personnel to administer COVID-19 therapeutics, including monoclonal antibodies.
- HHS expanding shelf life for bamlanivimab for an additional 6 months.

494 Review Final Annual Report

The board reviewed its final annual report for FY2021, which is published on the Division

496 Reports page.

Intern Jurisprudence Questionnaire

Ms. Carrillo will be working with Ms. Bell on the intern jurisprudence questionnaire to ensure it accurately reflects current statutes and regulations.

TASK 6

Ms. Carrillo and Ms. Bell will work on the intern jurisprudence questionnaire by the November 18-19, 2021 meeting. If edited before then, Ms. Carrillo will send the questionnaire to the board via OnBoard for voting.

COVID-19 matters

The board first addressed the PREP Act amendment, which is also on the board's agenda for tomorrow's legal opinion review. The board then addressed the topic ivermectin, which is included in the board's draft COVID Q/A presented to the board for their consideration to publish.

Ms. Bell stated the board needs to remain cognizant of what it publishes and be aware of potential liability issues, particularly when it comes to agents that are not EUA approved. Ms. Bell stated she is unsure if the board should create an opinion but agrees it doesn't help licensees or patients to be silent. Dr. Ruffridge stated it would be wise to address high dosage amounts because it tends to cause the most concern, adding that pharmacists are stuck on a front line making decisions to fill or not to fill, which leads to discussions on what role the pharmacist plays. Dr. Schaber stated the draft does a good job presenting all the facts together and gives good guidance to patients and pharmacists. Dr. Ruffridge commented that if the board were to publish this individually, it may find themselves front, center, and alone in the discussion, so wants to ensure the board thoroughly discusses this.

Dr. Ruffridge added that ivermectin falls into a gray area; that the reason why there is opposition is because there isn't clear evidence for its use. Dr. Ruffridge believes there should be a mechanism for knowing whether ivermectin has been a benefit or detriment to the patient, not only from the perspective of pharmacists, but in follow-up by the prescriber on how the patient fared with the drug. Dr. Ruffridge added that some ivermectin prescriptions are being issued by non-resident prescribers and wondered how that was being addressed by the medical board, particularly for remote prescribing.

Dr. Schaber mentioned receiving information from DHSS's section of epidemiology and inquired whether the board should work in tandem with this section to ensure there is consistency in the board's messaging. Dr. Ruffridge agreed it would be ideal to get DHSS' input and again see if prescribing boards would be amenable to collaborating on it.

On a motion duly made by Lana Bell to create and distribute a fact sheet on the use of ivermectin for the treatment of COVID-19 with feedback with DHSS' section of epidemiology, and seconded by James Henderson, it was:

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RESOLVED to proceed with pursuing a fact sheet on therapeutic treatment of COVID-19, including the use of ivermectin, in collaboration with DHSS' section of epidemiology.

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	APPROVE	DENY	ABSTAIN	ABSENT	
Leif Holm				X	
Ashley Schaber	X				
Justin Ruffridge	X				
Lana Bell	X				
Tammy Lindemuth				X	
James Henderson	X				
Sharon Long				X	

The motion passed with no further discussion.

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TASK 7

Laura will reach out to DHSS' section of epidemiology to collaborate with the board on its draft Q/A addressing therapeutic treatment of COVID-19, including the use of ivermectin.

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Agenda Item #9

Lunch

1:03 p.m.

Chair Ruffridge called for lunch at 1:03 p.m.

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Off record for lunch at 1:03 p.m.

564 On record from lunch at 1:40 p.m.

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Agenda Item #8

Board Business

1:41 p.m.

The board returned to board business to discuss the PDMP disciplinary matrix. The board reviewed its last approved matrix from their May 20-21, 2021 meeting, which included a plan for referring pharmacies to the investigative unit that appeared to not be complaint. Ms. Carrillo explained that until we understand which providers are dispensing and until reporters can benefit from a delayed reporting notification module, tracking compliance aggressively may need to be put on hold. Ms. Carrillo added that there still isn't an easy way to tell whether a delinquent reporter has since submitted or corrected their data. Ms. Sherrell reiterated the tedious process in synthesizing the volume of data into one spreadsheet. Dr. Schaber inquired what other boards' matrices look like, to which Ms. Carrillo stated we generally haven't delved into reporting compliance tracking because there are many unknowns with regards to who is direct dispensing.

The board discussed its reporting disciplinary matrix and agreed there is further discussion needed to implement a compliance tracking plan and matrix.

Agenda Item #11

Budget Report

2:08 p.m.

Melissa Dumas provided the board's budget report. The total expenditures for the 4th quarter is slightly over \$601,000, which was used for the board's fee analysis. Ms. Dumas explained the division's proposed fee adjustments, which includes decreases between 17% and 30%. Ms. Dumas explained that statute (AS 08.01.065) requires the division to annually review fees and determine whether expenditures and revenues are approximately equal. The division strives to maintain approximately one years' worth of revenue in reserves; however, fee setting is ultimately up to the director.

Ms. Dumas stated the board has an estimated biennium surplus of over \$1 million. Dr. Schaber inquired what happens to the board's budget when there is a surplus and over what period of time. Ms. Dumas stated the division as a whole essentially has one pot of money; when another program is in a deficit, the program is using the surplus of other programs. In reality, the board of pharmacy has its own budget, which currently has an ending cumulative surplus of \$614,000, which is being carried as a surplus every year.

 Dr. Ruffridge inquired whether the initial license fee could be adjusted. Ms. Dumas affirmed and posed options: does the board want current or existing licensees to bear the cost of running the program, or does the board want new and existing licensees to share the cost equally? Dr. Ruffridge stated the costs may hinder new licensees. Ms. Dumas suggested that if the board's goal is to encourage new technician applicants, both the initial and renewal fees could be adjusted. Ms. Dumas added that the fees take into account the number of licensees in that category. Dr. Schaber stated that cost may be a barrier to licensure, specifically for technicians.

Agenda Item #11

Industry/Profession Updates

2:32 p.m.

Molly Gray provided an update on events, including its Alaska Pharmacy Leadership Development program on September 24th, the Academy of Health-System Pharmacy Fall CE Conference on Saturday, September 25, which is being offered for 7.25 credits. The association is also partnering with the University of Alaska/Idaho State University (UAA/ISU) Doctor of Pharmacy Program. This partnership includes a change in the association's Executive Director position for AKPhA, which will now be a shared position with the UAA/ISU Doctor of Pharmacy Program. Ms. Gray also announced that she will be leaving the association with her last day being the 25th.

 Caren Robinson provided a legislative update on telehealth, adding that some influences may weigh down and cloud the initial intent of this bill. Ms. Gray also added that the association will continue to progress efforts on white bagging and expanding pharmacists' authority for the next session.

621 622 Agenda Item #10 Subcommittee Updates 2:42 p.m. 623 624 PDMP board chairs Chair Ruffridge stated these meetings are continuing to occur twice per month for inter-board 625 communication on issues related to the database and compliance with it. Dr. Ruffridge added 626 there's been discussions on how to identify the "bad actors" through use of a new provider outlier 627 628 module. 629 630 Healthcare board chairs 631 Dr. Ruffridge stated COVID-19 continues to be the main topic of discussion at this meeting. The 632 overall take-home is to acknowledge the work healthcare workers are doing to respond to the 633 ongoing pandemic, particularly in hospital settings. 634 **CSAC** 635 There was no update. 636 637 638 Compounding Subcommittee 639 There was no update. 640 641 **Administrative Business** 2:46 p.m. Agenda Item #13 642 643 A bit ahead of schedule, Dr. Ruffridge called for license statistics. 644 645 License statistics 646 Ms. Carrillo stated there are still emergency permit applications coming in for pharmacists, interns, 647 and technicians. At present, there are 23 active pharmacist permits, 5 technician permits, and 1 648 intern. Ms. Carrillo also added that courtesy licenses are no longer being issued because applicants 649 can now apply for a permanent license, given the PREP Act allows these individuals to administer 650 COVID-19 vaccines. 651 652 Form updates – inspection discrepancy The first form update included a draft pharmacy/facility inspection discrepancy form. Ms. Carrillo 653 654 recalled from the board's May meeting discussions regarding a revised inspection process, which 655 would include the board's assigned investigator. The board previously discussed options on how 656 to handle pharmacy findings and deliberated potential acknowledgment requirements for 657 pharmacies should findings occur. 658

One option was to require pharmacies to sign an inspection discrepancy form acknowledging the

issues will be corrected and another option was to submit an acknowledgement form including documents demonstrating the issues indeed were corrected. Another option discussed was a

combination of both; to submit an acknowledgement form attesting that the issues will be

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corrected within a certain timeframe, and then a subsequent submission showing proof the corrections were made. The draft included in the packet was the first option.

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Dr. Ruffridge commented that this could be a mechanism to track patterns of inspection issues and to address them accordingly. Ms. Carrillo suggested the board could include in its disciplinary matrix a threshold to address appropriate action, e.g.: x occurrences within y timeframe will be treated with z action. Ms. Carrillo stated the board would need to finalize language to further inform the process and to align the inspection form with.

670 671

Form updates – pharmacist reinstatement

Ms. Carrillo shared that this form was updated to reflect the qualifying years for which a
 pharmacist can apply for reinstatement, which is when a license has lapsed for more than two but

less than five years.

676 677

Form updates – PIC/facility manager

The incoming and outgoing forms were updated to include pharmacist-in-charge language as the previous version was confusing in its use of language for facility managers only.

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<u>Task list</u>

The board reviewed the task list. There were 34 tasks from the May meeting and two carry-over tasks from February. The majority of tasks were complete and remaining tasks will be ongoing.

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Ms. Bell addressed task #6, providing the update that she met with Investigator Bowles twice and on one of those occasions, with the new PDMP investigator, Brenda Smith. Ms. Bell stated she would be updating the inspection checklist. Ms. Bell then provided an update on task #33, stating it was in relation to a pharmacist who wanted to work with AIDS patients with autonomy and that it required a collaborative practice agreement. The board then discussed new tasks.

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TASK 8

Dr. Schaber and Ms. Carrillo will meet to work on a draft disciplinary matrix in preparation for board discussion during its November 18-19, 2021 meeting.

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TASK 9

696 Dr. Ruffridge will take over the expiration date project in 12 AAC 52.480.

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TASK 10

Ms. Carrillo will send a poll via email to confirm availability for the November 18-19, 2021 meeting.

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Travel/conferences/workshops

703 There were no upcoming board member travel requests for out-of-state training or conferences;

however, Ms. Carrillo stated there were some PDMP related travel Ms. Sherrell would be

participating in, including the NASCSA conference in October.

Ahead of schedule, the board returned to discussion on the PDMP disciplinary matrix. Mr. Henderson inquired how the board would quantify dollar amounts for fines related to a variety of actions the board could choose to take. Dr. Ruffridge suggested there may need to be some prioritizing of what types of licensees and violations to refer.

Dr. Ruffridge and Mr. Henderson discussed limitations with data visibility and lingering frustrations with dialing into certain datapoints that conceptually would seem simple but in reality, is difficult and time-consuming. Dr. Ruffridge emphasized that the difficulty of data mining may hinder the board's ability to articulate to the legislature the changes that may need to occur to make the system more effective. Dr. Ruffridge acknowledge the database contains an inordinate amount of data that may be directly contributing to analytics delays.

Ms. Sherrell agreed there were some functionalities needing to be assessed but did share there were some improvements underway to make analysis easier. Ms. Sherrell added that as of Tuesday, September 21st, there appeared to be less than 100 delinquent pharmacies. Ms. Carrillo clarified this was out of 800 potential delinquent submitters, with pharmacies constituting a small percentage, but that the total # of delinquent submitters may be skewed by providers who are not required to submit.

Dr. Ruffridge revisited establishing a tiered system where there are levels of action taken and fines imposed commensurate with the severity or frequency of the delinquency, e.g.: \$200 for the first violation and \$500 for the second. Ms. Carrillo commented that compliance monitoring may need to be simplified to assess the presence or absence of a violation rather than assessing based on level of egregiousness. The other consideration was reviewing compliance every day since the system isn't currently capable of searching within a tailored timeframe.

Dr. Ruffridge entertained random audits of PDMP compliance. Mr. Henderson agreed it would be a way to make the large volume of data more manageable and Dr. Schaber also expressed support for this approach. Ms. Carrillo said it could work in the same way continuing education audits work: 5% of randomly selected licensees would be audited for compliance through reports generated within the licensing system, and if the licensee fails the audit, a consent agreement and fine could be pursued. Mr. Henderson suggested that if a licensee fails an audit, they automatically audited be audited in the next renewal, to which Dr. Ruffridge agreed.

Ms. Carrillo's initial idea is that licensees appearing on the audit would be searched in the PDMP based on the DEA number, which would generate reports on daily compliance. The system currently allows a three-year lookback period by quarter. Ms. Carrillo estimates that 5% of licensees would be 24 pharmacies, but the board could determine how often to run these audits. Notices to licensees advising them the new process would be taking place was recommended and it was noted the delinquent reporting module would help prime reporters to report daily.

Agenda Item #14 Public Comment #2 3:45 p.m. There were no public comments. **Board Business** Agenda Item #8 4:02 p.m. The board returned to discussing the PDMP disciplinary matrix. Ms. Carrillo stated she would need to double check on whether a regulation change in 12 AAC 52 is permitted since the existing CE audit language is in centralized regulations, 12 AAC 02. **TASK 11** Ms. Carrillo will inquire with the regulation specialist or Department of Law as to whether the board can adopt PDMP audit regulations under 12 AAC 52 instead of 12 AAC 02. Agenda Item #15 **Recess** 4:06 p.m. Chair Ruffridge recessed the meeting at 4:06 p.m. and will resume the meeting at 9:00 a.m. on Friday, September 24th.

	State of Alaska t of Commerce, Community and Eco of Corporations, Business and Profes	
	Alaska Board of Pharmacy	
M	INUTES OF THE EMERGENCY N	MEETING
	September 23-24, 2021 Videoconfe	rence
Article 6, a schedul	08.01.070(2), and in compliance with the description of the Board of Pharmacy are to the COVID-19 pandemic, in-per	via videoconference on
Agenda Item 1	Call to Order/Roll Call	Time: 9:46 a.m.
The day 2, September 9:46 a.m.	24, 2021 videoconference was called to ord	der by Chair, Dr. Ruffridge at
Board members preser	nt, constituting a quorum:	
I .' D .CC ' 1	DI D #DITAD4707	
	e, PharmD #PHAP1787	
Lana Bell, RPh	, PharmD, #PHAP1697	
•	#PHAP93 on, RPh #PHAP1683	
James Tienders	OII, KFII #F11AF1003	
Division staff present:		
Division stair present.		
Laura Carrillo.	Executive Administrator (joined at 10:40 a.r	n.)
	Occupational Licensing Examiner	/
Lisa Sherrell, P	•	
Sara Chambers	S	
	,	
Members from the pu	olic present/registered:	
-1		
Pamela Samash	, The people	
Olga Brophy, O	1 1	
Michael Coons	, Matsu Chapter, AMAC Action	
	TelePharm a Cardinal Health Company	
Kendra Croker	, Cardinal health	
Caren Robinso	n, AkPha	

Christopher Kurka, Office of Rep. Kurka
Samantha Chessie, Animal Policy Group
Hannah Muasher, University of Arizona College of Pharmacy
Kevin McCabe, Alaska House of Representatives
Reggie Dilliard, Gladstone
Gordon DeVries, Concerned Citizen

Agenda Item 2 Review/Approve Agenda

Time: 9:52 a.m.

Time: 9:55 a.m.

Time: 10:02 a.m.

The board reviewed the day 2 meeting agenda. Dr. Ruffridge called for a motion.

On a motion duly made by Lana Bell to approve the meeting agenda, seconded by Ashley Schaber, and approved unanimously, it was:

RESOLVED to accept the September 24th meeting agenda as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson	X			
Ashley Schaber	X			
Leif Holm				X
Sharon Long				X

The motion passed with no further discussion.

Agenda Item 3 <u>Ethics Disclosures</u>

As with day 1, Dr. Schaber disclosed that she is a member of AKPhA and the Past-President (incl. Board Member; By-Laws & Nominations Committee Chair) (through 2/22); Co-treasurer (through 2/22); and a member of the Legislative & Convention Committees.

Agenda Item 4 Public Comment #3

Representative McCabe:

Several pharmacist claim they are being threatened by this board or possibly by federal agencies because ivermectin is claimed to be contraindicated for COVID-19, even though the NIH states it is a better therapeutic option than remdesivir. I think the board of pharmacy can at least get out of the doctors' way. I did read the board's draft statement, though I would suggest there be a link to the NIH website. I know pharmacists are last line of defense for mistakes with codeine and heroin and those sorts of drugs, but since the FDA has approved it for other diseases, pharmacists should

be part of the solution by letting prescribers do their jobs. It is effective in India and Scotland, so I would appreciate this to be considered in the board's draft.

Pamela Samash:

I was hoping to hear the conversation regarding your response to Representative McCabe. I want to encourage you to really consider allowing ivermectin and malaria drugs to be available to the public because it would take pressure off of the hospitals. I keep hearing that hospitals are overwhelmed, and how some states are importing foreign healthcare workers. I think we should try instead to keep people as healthy at home as possible. What we are doing at home is putting together a COVID test kit. The kit was suggested by Trump's doctor who is going for a Nobel Prize- he has a list of things that can be taken for preventative measures. The board should consider issuing COVID kits.

Michael Coons:

I am a retired United States Air Force serviceman and was in Honduras were it was a highly malaria-infested country. I ended up taking hydroxychloroquine and took it for the 90-day duration I was there as well as upon my return to the states. I had zero problems with taking this drug off label. There isn't just anecdotal evidence that it works, like with President Trump, that is an actual person who has benefited from this drug. I'm also a commissioner on the commission on aging, so I'm concerned about seniors. I'm also the president of the Matsu chapter of the Association of Mature American Citizens (MAC). As seniors, we need to have the ability to get treatment we need. My doctor has no problem giving my hydroxychloroquine or ivermectin, but Fred Meyer, Carrs, and Walgreens are flat out refusing out of worry their license will be revoked by the CDC. The CDC does not have anything to do with licensure, but the board has everything to do with it. The bottom line is that when a patient and doctor has decided on a treatment, it is the pharmacy's job that the medication won't cause any adverse action or will contact the prescriber if there are concerns. Ultimately the pharmacy must dispense the drug.

Agenda Item 5

Legal Opinion Updates

The board then moved to reviewing legal opinion updates.

Drug takeback programs (guidance complete):

The guidance provided back on this request on June 3, 2021 is that the board can implement regulations for drug takeback programs and can require that pharmacies notify the board when they have become a receptacle site. Dr. Ruffridge stated the board could continue to look into whether they would like to adopt regulations to implement this.

TASK 12

914 Ms. Carrillo will add drug takeback programs to the board's agenda for November to determine 915 whether the board intends to pursue this in regulation.

Delegate reporting (guidance pending):

Time: 9:50 a.m.

- The request to DOL for clarification was to understand whether pharmacies and individual prescribers can delegate reporting to third-party fulfillment companies. Ms. Sherrell explained that currently, we verify that the primary contact for the data submitter is the PIC because statute requires that they report on behalf of the pharmacy. In reality, many pharmacies are set up to report automatically for pharmacies and provider clinics/institutions. The ways this typically happens is the pharmacy's corporate IT gives permission to the vendor to take their dispensation data and transmit it to ClearingHouse (the PDMP data reporting repository), so that it can be uploaded as a secure file transfer protocol (STFP) on a daily basis.
- Ms. Sherrell further explained that it doesn't make sense to only accept data submissions when the primary contact is a PIC because if the contact is a regulatory, IT, or third-party individual, which often is the case, denying their data submission based on the wording of the statute would effectively prevent required patient data from being included in the PDMP. Ms. Sherrell stated we are still waiting for a response from DOL.

TASK 13

Ms. Carrillo or Lisa Sherrell will follow-up with DOL as to whether third-party vendors can report on behalf of pharmacies and prescribers given delegates must be licensed under AS 08, and third-party vendors are not.

PDMP reviewing and authorized refills (complete):

When looking at reviewing requirements in AS 17.30.200(k)(4)(B), DOL clarified that prescribers are exempt from reviewing controlled substance prescriptions written for 3+ days only if they do not contain any authorized refills.

DOL also clarified that emergency providers are not blanket exempt from the review requirement, which has been a misunderstanding. If an emergency provider issues a schedule II or III controlled substance, it is not in a scenario included in AS 17.30.200(k)(4)(A) and written for more than a 3-day supply, that provider must review the patient's prescription history.

The board reviewed DOL's explanation that there is no preemption of federal rule, 75 CFR Sec. 1306.22, on the board's ability to refill schedule III controlled substances after more than 6 months of the original date of issue that doesn't exceed 5 refills. The response further stated federal law sets the floor but gives states the ability to be more stringent, but that the board had opted to restrict pharmacists and interns from exercising discretion to dispense any quantity of a schedule II-IV controlled substance. Dr. Ruffridge's understanding was there was discretion in regulation, to which Mr. Henderson agreed but noted the response from DOL seems to indicate there is no discretion; prescriptions must be filled in the quantity indicated on the order. Dr. Schaber pointed to 12 AAC 52.465, which does allow the pharmacist to dispense a lesser quantity of a schedule II.

In further read of regulation 12 AAC 52.470, Dr. Ruffridge noted it states refills can be dispensed in any quantity but only for non-controlled substances. Chair Ruffridge inquired to the board as to whether they wish to pursue potential changes to this section.

TASK 14

Ms. Carrillo will add refills of controlled substances to the board's agenda for November to determine whether the board intends to pursue this in regulation.

<u>Medical examiner + investigator access (complete):</u>

Guidance previously provided to the board in 2018 stated that medical examiner delegates could access the database on behalf of the medical examiner/coroner's office. The follow-up question to the initial assessment was whether a subpoena was required either by the ME/C or the delegate, e.g.: medicolegal investigator. Ms. Sherrell stated these staff are not licensed under AS 08 but are state employees. DOL's response was that only the ME/C could access the data to determine cause of death without a subpoena, but that delegates cannot access the data either with a subpoena or without, since their duty is not to determine cause of death, which is the responsibility of the ME/C.

DOL suggested the board amend their regulations to clarify only medical examiners can have access to the system upon a written request for access.

TASK 15

Ms. Carrillo will add ME/C and delegation to unlicensed support staff to the board's agenda for November to determine whether the board intends to pursue this in regulation.

Agenda Item 6 Regulations

Laura Carrillo joined the meeting at 10:45 a.m.

The board then moved to discussion regulations, including reviewing public comments.

Regulations overview

The board reviewed the steps in the regulation process, including steps in the regulations process and the effective regulations approach.

PDMP regulations: 12 AAC 52.855

These regulations went into effect on May 6, 2021 and included language pertaining the required timeframe to register with the system and clarified the mechanism for which to be assigned a unique PDMP account. Dr. Ruffridge read each comment, which were included in the board packet, out loud for the record.

PDMP regulations: 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857

Time: 10:24 a.m.

1001 These regulations went out for public comment through September 16, 2021 and includes 1002 additional changes to registration, creates a section on renewal requirements, and adds language 1003 requiring pharmacies and pharmacists to notify the board when there is a change in dispensing status. These regulations were ready for adoption. 1004

1005 1006 **TASK 16**

> Ms. Carrillo will include the affidavit of board action and certification order for the board to entertain a motion adopting changes to 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857 during the November 18-19, 2021 meeting.

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PDMP regulations: uniform agreement

1012 Dr. Ruffridge informed the board this topic relates to an ongoing discussion with PDMP-affected boards. Dr. Ruffridge explained that the intent is for the boards to identify and come to a 1013 consensus on specific matters for which to prioritize and pursue investigations on, such as 1014 egregious prescribing/dispensing matters, high MMEs, dangerous combination therapies, over-1015 prescribing, etc. Dr. Schaber expressed her support, stating that a unified approach with prescribing boards is a useful and ideal approach both for the public and profession. If regulations 1017 need to be amended to align with the agreement, the board will pursue that. 1018

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Dr. Ruffridge commented the Board of Pharmacy doesn't have the ability to enforce or discipline prescribers, but that because the PDMP is statutorily housed under the board, it is appropriate and obligated to pursue a uniform agreement with regards to best practices. Dr. Ruffridge asked whether other members had specific ideas on what else could be included in the agreement. Mr. Henderson expressed support for the criteria Dr. Ruffridge mentioned, adding that too many thresholds may complicate standardization.

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1030 1031 Ms. Sherrell provided an example of variation amongst boards where standardization would be useful; the State Medical Board has set a 50 MME limit whereas the Board of Dental Examiners has set a 60 MME. Ms. Sherrell also discussed the 5-5-3 rule (5 or more prescriptions from 5 or more prescribers/pharmacies within a 3-month period), and informed the board that when recently testing the provider outlier module, it was found patients going to 2 or more pharmacies was where the highest risks was occurring.

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Dr. Schaber commented on the uniform agreement and the 5-5-3 rule, which Ms. Sherrell previously explained has been the board's criteria in the past, but that other states have different threshold levels. Dr. Schaber stated it may make sense to lower this criteria because of the geographical distribution of pharmacies across the state. Ms. Carrillo stated the 5-5-3 rule was voted on during the board of pharmacy during a meeting in 2014 because at the time, that was a common threshold amongst other states, but suggested since it was voted previously, that a change to this should be on the record for consistency. Mr. Henderson inquired how many alerts were triggered for meeting this threshold, to which Ms. Sherrell stated there were 61. Dr. Ruffridge inquired how this alert is documented, which Ms. Sherrell explained appears in the patient's record as an alert.

1044 TASK 17

Ms. Sherrell will poll other states, specifically those with geographic/accessibility similarities, on what criteria they use for the doctor shopper alert and provide the board the information by their November meeting.

- National certification notification
- Ms. Bell explained that pharmacies, specifically the PIC, should verify that a technician is nationally certified. Ms. Carrillo recalled the board came to a consensus to repeal and readopt 12 AAC 52.990, which would effectively require licensees to provide copies of any credentials they hold, including licenses, registrations and certifications. Ms. Bell inquired if the license certificate indicates

Ms. Bell added she's been discussing with the state that there are two categories of technicians: those who are nationally certified and those who are not. Dr. Ruffridge stated the board's regulations covers the responsibility of the PIC to ensure nationally certified techs are delegated duties only for which they are trained for. Dr. Ruffridge added that one PIC on duty may feel that pharmacy technician is qualified whereas another PIC on duty may not be comfortable with that technician performing the same duties.

Ms. Carrillo stated there was guidance provided by LAW that a separate license category for nationally certified pharmacy technicians requires a statute change. Dr. Schaber supports designating two separate categories because technicians are leaving their employers due to lower pay rates. Dr. Schaber provided examples with laboratory technicians and x-ray technicians who are nationally certified and therefore are entitled to higher pay, adding that creating a separate category may help with retention. Dr. Ruffridge also supports adding this to their statute project.

Regulations for recommended approval

Dr. Ruffridge went over the recommended approval document located in the packet, which included a summary of proposed changes the board has previously expressed support on but have not yet moved forward through the adoption process.

- 12 AAC 52.020 (facility license) no other proposed changes
- 12 AAC 52.030 (change of facility location or name) no other proposed changes
- 12 AAC 52.040 (change of facility ownership) no other proposed changes
- 12 AAC 52.070 (pharmacist license by exam) no other proposed changes
- 12 AAC 52.092 (pharmacist approval to sit for exam) no other proposed changes
- 12 AAC 52.095 (pharmacist license by reciprocity) Ms. Bell commented there should still be a verification of the status of all licenses in which the applicant holds or has ever held a license. Ms. Bell's concern is that the license from which the applicant is seeking reciprocity from may be in good standing, but that other states in which the applicant holds a license may not be. Dr. Schaber expressed similar concerns. Dr. Ruffridge referred to AS 08.80.145 which requires the applicant to provide proof the applicant has not been

disciplined. It is not the intent to disqualify an applicant from being licensed if they have been disciplined, but Ms. Carrillo stated this is covered in question #1 of the professional fitness section. The board may choose to license with conditions. Ultimately, there were no other proposed changes.

- 12 AAC 52.080 (internship requirements) no other proposed changes
- 12 AAC 52.120 (pharmacist intern license) no other proposed changes
- 12 AAC 52.130 (out-of-state pharmacies) no other proposed changes
- 12 AAC 52.140 (pharmacy technician license) no other proposed changes
- 12 AAC 52.200 (pharmacist-in-charge) Dr. Ruffridge inquired whether there should be a limit as to the number of pharmacies a PIC can be in charge of. Mr. Henderson recalled previous discussions on the hour requirement in which a PIC must be present and Ms. Carrillo stated this question has come up before as there seemed to be a need to clarify this in regulation. Dr. Schaber agreed it would be reasonable to set a limit. Ms. Bell suggested such restrictions should just apply to central and remote pharmacies. Ms. Carrillo also shared pharmacists have also inquired whether there is a minimum amount of time for how long they must be physically present at a pharmacy for, to Dr. Ruffridge stated confirmed there is no requirement in regulation.
- 12 AAC 52.230 (pharmacy technician functions) no other proposed changes
- 12 AAC 52.300 (license renewal) no other proposed changes
- 12 AAC 52.585 (mandatory patient counseling) no other proposed changes
- 12 AAC 52.610 (wholesale drug distributor license) no other proposed changes
- 12 AAC 52.696 (outsourcing facility license) no other proposed changes
- 12 AAC 52.697 (third-party logistics provider license) no other proposed changes
- 12 AAC 52.993 (executive administrator) no other proposed changes

TASK 18

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Ms. Carrillo will send a copy of the motion and draft wording for the board's large regulation project for review by Department of Law and for public comment.

1115 <u>Emergency permit – 12 AAC 52.110</u>

- 1116 Ms. Carrillo addressed the board's emergency permit and courtesy license regulations in 12 AAC
- 1117 52.110, inquiring whether in (a), a pharmacy can even operate if there is no pharmacist available,
- explaining that as written, technicians and interns can only apply for a permit if there is no
- 1119 pharmacist on staff. Dr. Ruffridge agreed this needed correction, stating it should say that the
- absence of pharmacy *personnel* and not a *pharmacist* constitutes a need for a permit. The board
- 1121 further discussed changes to this section, including repealing (d) relating to courtesy licenses since
- adjustments to the emergency permit to quickly staff the pharmacy would make the courtesy
- 1123 license moot.
- 1125 The regulation also states a permit can be applied for under other emergency circumstances. Ms.
- 1126 Carrillo asked the board to clarify what other circumstances constitutes an emergency. Dr.
- 1127 Ruffridge suggested it may be an emergency declaration, such as our current pandemic, but

recalled the intent of the permit is to quickly staff a pharmacy with personnel e.g.: in the event staff must quarantine.

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- Ms. Carrillo added that there seems to be an opportunity for applicants to attest to being qualified by having an existing license in another state; however, there is no requirement to provide documentation. Dr. Ruffridge expressed there should be no self-attestation and instead require verification of licensure. The board continued to discuss emergency permit language changes, including changing the duration of the language from 90 days to 120 days. Ms. Carrillo stated she
- would draft language during lunch for the board to consider.

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- 1138 TASK 19
- Ms. Carrillo will draft language to amend the emergency permit regulation, 12 AAC 52.110 to replace "pharmacist" in (a) with "pharmacy personnel".

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1142 Agenda Item 7 <u>Lunch</u>

Time: 12:31 p.m.

Time: 1:03 p.m.

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- 1144 Chair Ruffridge called for lunch at 12:31 p.m.
- Off record for lunch at 1:03 p.m.

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1147 Agenda Item 6 Regulations

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Prior to lunch, the board concluded review of proposed changes to their large regulations project. Upon return from lunch and with no further comments on this project, the board was ready to entertain a motion.

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1153 On a motion duly made by Lana Bell, seconded by Ashley Schaber, and approved unanimously to accept changes to 12 AAC 52.020, 12 AAC 52.030, 12 AAC 52.040, 12 AAC 1154 52.070, 12 AAC 52.092, 12 AAC 52.095, 12 AAC 52.080, 12 AAC 52.120, 12 AAC 52.130, 12 1155 1156 AAC 52.140, 12 AAC 52.200, 12 AAC 52.230, 12 AAC 52.300, 12 AAC 52.585, 12 AAC 52.610, 12 AAC 52.696, 12 AAC 52.697, 12 AAC 52.993 as discussed on record, and for the 1157 1158 amendments to be forwarded to the Department of Law for cursory review before 1159 releasing changes to the public for written comment for board consideration during its 1160 November 18-19, 2021, it was:

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RESOLVED to accept the changes to 12 AAC 52.020, 12 AAC 52.030, 12 AAC 52.040, 12 AAC 52.070, 12 AAC 52.092, 12 AAC 52.095, 12 AAC 52.080, 12 AAC 52.120, 12 AAC 52.130, 12 AAC 52.140, 12 AAC 52.200, 12 AAC 52.230, 12 AAC 52.300, 12 AAC 52.585, 12 AAC 52.610, 12 AAC 52.696, 12 AAC 52.697, 12 AAC 52.993 for review by LAW and to release amendments for written public comment.

1168		APPROVE	DENY	ABSTAIN	ABSENT	
1169	Justin Ruffridge	X				
1170	Lana Bell	X				

1171	Tammy Lindemuth		X
1172	James Henderson	X	
1173	Ashley Schaber	X	
1174	Leif Holm		X
1175	Sharon Long		X

The motion passed without further discussion; however, it was noted remaining proposed changes in the large regulation packet were not ready to move forward. This includes language related to veterinary prescriptions, automated kiosks, security, and substitution.

TASK 20

Ms. Carrillo will add prescription drug order information, veterinary prescriptions, automated kiosks, security, and substitution to the board's agenda for regulations discussion at the November meeting.

Collaborative practice agreements

Dr. Ruffridge inquired about an update on proposed changes to collaborative (cooperative) practice agreements, which includes the medical board's proposal to repeal language in their regulation, 12 AAC 40.983. Ms. Carrillo stated that as currently written, the regulation requires these agreements to be approved by the full Board of Pharmacy as well as the State Medical Board; however, the board of pharmacy's intent has been to administratively approve these. Dr. Ruffridge clarified for the board that the proposed changes went out for public comment and ended on the end of July 29. Ms. Carrillo stated she would follow-up on the status of this change.

Ms. Carrillo then addressed proposed corresponding amendments to the board's regulations, 12 AAC 52.240, which reflects significant deletions. Ms. Carrillo clarified the language markups are duplicative of what currently exists in the medical board's regulations and would be appropriate changes to make should their proposed changes take effect. Dr. Ruffridge inquired whether the board could preemptively approve this language, to which Ms. Carrillo stated seems reasonable.

TASK 21

Ms. Carrillo will follow up with the division's regulation specialist on the status of proposed changes to 12 AAC 40.983 dealing with physician-pharmacist practice agreements.

TASK 22

Ms. Carrillo will submit to the regulation specialist the board's proposed corresponding regulation changes for collaborative practice agreements in 12 AAC 52.240 once 12 AAC 40.983 takes effect.

 On a motion duly made by Lana Bell, seconded by Ashley Schaber, and approved unanimously to preemptively accept changes to 12 AAC 52.240 dealing with simplifying collaborative practice authority in anticipation of corresponding changes in the State Medical Board's regulations, 12 AAC 40.983.

RESOLVED to accept the changes to 12 AAC 52.240 to be sent to the regulation specialist once changes to 12 AAC 40.983 are in effect.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson	X			
Ashley Schaber	X			
Leif Holm				X
Sharon Long				X
The motion passed	with a question fro	om Dr. Schaber,	who inquired abou	t the differences and

The motion passed with a question from Dr. Schaber, who inquired about the differences and similarities chart included in the board's packet. Ms. Carrillo affirmed, stated she created the chart to analyze differences and similarities between the medical and pharmacy boards' language, which was used to make proposed deletions to 12 AAC 52.240.

Board of nursing letter update

The board then moved to discussing the board's letter to the State Board of Nursing relating to prescription order requirements in 12 AAC 44.440(c)(2), which states that a valid prescription from an APRN must include their credentials, e.g.: license #. This has raised the question as to whether pharmacists can legally dispense prescriptions absent this information. Ms. Carrillo provided an excerpt of the Board of Nursing's discussion from their August 4, 2021 meeting, but noted there was not yet proposed language to provide the board with.

TASK 23

Ms. Carrillo will follow-up with the Board of Nursing on the status of addressing 12 AAC 44.440(c)(2) dealing with required credentials on drug order.

Military licensing

Included in the board's packet was draft military language Ms. Carrillo provided for the board's initial deliberation in advance of Director Chambers joining the meeting to discuss the military license bill, SB 21. Ms. Carrillo explained the draft regulatory language aligned with bill language to identify and accept equivalent military training in lieu of traditional academic/onsite training.

The draft outlined potential application checklist requirements, military extension criteria, and alternatively acceptable education and experience, but also proposed repealing the temporary pharmacist license in 12 AAC 52.100. This repeal is suggested because the new military language would replace that section. Ms. Carrillo explained that the temporary license is not effective as a means to quickly obtain licensure due to the requirement to take and pass the national exams, which is also required for permanent licensure. The temporary license is also valid for 90 days, whereas the military license bill provides a minimum of 180 days. Ms. Carrillo clarified the draft wasn't necessarily to be approved by the board but rather was to serve as a starting point.

Dr. Ruffridge inquired how the military license is different from the board's existing reciprocity 1255 1256 application. Ms. Carrillo stated the military license is to be issued on an expedited basis, but added 1257 that the division already has a process in place: when applications for expedited military or military spouse licensure are received, they are scanned into the licensing system as an expedited military 1258 application and are therefore prioritized. Ms. Bell added there has been a push for a few years to 1259 acknowledge Alaska's strong military presence by formalizing the expedited applications under the 1260 1261 statute, AS 08.01.063. Dr. Ruffridge acknowledged this obligation to expand licensure during an all-time high of expediting applications during the current pandemic, but also recognized and 1262 expressed concern that the division staff was seemingly at an all-time low. Ms. Bell reiterated 1263 boards are being compelled by legislation to participate, that it is not optional. The legislation takes 1264 1265 effect in January 2022.

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The board will return to military regulation discussions following Director Chambers' presentation.

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Agenda Item 8 Statute Projects

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Affidavits of moral character

This requirement is in AS 08.80.110 and AS 08.80.145 for licensure via examination and reciprocity, respectively. Dr. Ruffridge acknowledge this was a requirement that seems to be unnecessary as it does little to help boards assess competency. This is an area the board continues to pursue repealing through legislation.

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White bagging

- Dr. Schaber provided an overview that this practice involves an insurance payer requiring the medication to go through the specialty pharmacy or pharmacy of the insurance
- 1281 S choice hospital instead of the pharmacy, adding it is complicated and time-consuming for staff.
- Dr. Schaber stated the biggest issue is that the pharmacy that's preparing the medication and
- 1283 dispensing it to the patient isn't getting paid for that medication because it's going through the
- specialty pharmacy. This results in a financial impact, specifically to infusion pharmacies. Dr.
- Schaber added that the AKPhA is working on draft language for a statute change and that the association acknowledges it will need to go through the Division of Insurance.

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Dr. Ruffridge expressed support for limiting or prohibiting this practice, stating it seems to also fall within the Board of Pharmacy's purview to address with regards to liability and safety. Dr. Schaber stated there is also brown bagging, which is when medication is shipped to the patient, and the patient then goes to the hospital or clinic to have administered there. Brown bagging is different from white bagging in that only the latter involves direct shipment to the patient. Mr.

1293 Henderson stated he does see this occasionally in his practice.

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TASK 24

Dr. Schaber will provide model language from the AKPhA on the issue of white bagging to share with the board.

Time: 1:36 p.m.

1298 TASK 25

1299 The board will continue to address white bagging at its November 18-19, 2021 meeting.

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Internet pharmacies

Dr. Ruffridge reviewed materials in the packet related to online pharmacies and the NABP's research findings showing that 96% of Internet sites were operating in conflict with pharmacy laws and practice standards. Ms. Carrillo stated this topic was looked at a few years ago but that there has been recent concern about where patients are receiving their prescriptions from, whether online from outside of Alaska or through out-of-state pharmacies not registered by the board.

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Ms. Carrillo explained that the NABP's .Pharmacy Verified Websites Program is a solution allowing regulatory bodies to confirm whether an online mail order pharmacy has been vetted by and verified by the NABP as a safe and alternative source to obtain prescriptions. Dr. Ruffridge acknowledged there are a huge number of medications being shipped into Alaska from online sources and that it would helpful to know if there are any states that have had success participating with the program.

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1315 TASK 26

Ms. Carrillo will reach out to the NABP for success stories from states that have participated in the .Pharmacy Verified Websites Program.

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1319 Chair Ruffridge called for break.

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- 1321 *Off record at 1:57 p.m.*
- 1322 On record at 2:04 p.m.

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1324 Agenda Item 9

Military Licensing Statutes

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1326 <u>Military licensing</u>

Director Chambers joined the board to provide an overview of military licensing, which has been in statute as optional for boards to adopt additional regulations on. Director Chambers informed the board that after increased encouragement throughout the state, the legislature changed the wording from being an encouragement to a mandate. Director Chambers stated this change is a result of continuous feedback that the military is suffering because of a lack of support from communities in which they're based, that ultimately this legislation aims to help military members and military spouses to quickly work following relocation.

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Director Chambers stated the biggest piece of this legislation and area potentially needing the most deliberation on is evaluating for substantially equivalent experience. As already written, the statute will require the applicant to be licensed elsewhere without discipline from a state has substantially the same licensure requirements as Alaska. Ms. Chambers stated programs are required to both accept military training and education towards licensure and issue licenses on an expedited basis per AS 08.01.064.

Time: 2:01 p.m.

Dr. Ruffridge stated that clarification is needed on how military language is different from emergency licensing language and whether there is an opportunity to amend existing language there. Ms. Chambers agreed, stating the Medical Board is also thinking about language they already have that can be expanded to incorporate this. For next steps, Director Chambers suggested the board could appoint a member to take ownership of the project, stating it would be ideal for the board to make an actionable assignment for discussion at its next meeting. The other option is to delegate the task to EA, Ms. Carrillo, who can then work with her on fine tuning the language.

Agenda Item 6 Regulations Time: 2:24 p.m.

Following the presentation of military licensing with Director Chambers, the board returned to discussing amendments to the board's existing emergency regulation section, 12 AAC 52.110. Dr. Ruffridge agreed using the existing tools may be more efficient. As previously discussed, the division has existing forms, 08-4850 and 08-4633, to request expedited processing for military members and spouse of military members, which currently must be submitted with permanent applications. Ms. Bell expressed concerns with duplicating work and creating new requirements for a process that already exists. Mr. Henderson also expressed support for using existing forms to fast-track these.

The board continued to discuss changes, including substantially equivalent language and the administrative process to ensure military applications can be prioritized. Dr. Schaber also expressed support for this direction. Ultimately, the board agreed using the division's existing cover forms for military spouse and active duty military personnel in addition to submitting a military courtesy license form was reasonable.

 On a motion duly made by Ashley Schaber, seconded by Lana Bell, and approved unanimously to accept the military and emergency permit language amendments to 12 AAC 52.110 as discussed on record to be sent for cursory review by Department of Law, and for written public comments to be returned for board considered during its November 18-19, 2021 meeting, it was:

RESOLVED to accept the changes to 12 AAC 52.110 for review by LAW and released for public comment.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				X
Ashley Schaber	X			
Justin Ruffridge	X			
Lana Bell	X			
Tammy Lindemuth				X
James Henderson			X	
Sharon Long				X

1383 1384	The motion passed with no further discussion.
1385	TASK 27
1386 1387	Ms. Carrillo will send the draft language and motion excerpt regarding military courtesy and emergency courtesy changes to 12 AAC 52.110 to the regulation specialist.
1388	emergency courtesy changes to 12 11100 32.110 to the regulation specialist.
1389 1390	(Words in boldface and underlined indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted.)
1391	binackereb] indicate language being deleted.)
1392	12 AAC 52.110 is amended to read:
1393	12 AAC 52.110. Emergency and military courtesy licensure to practice as a pharmacist,
1394	pharmacy intern, or pharmacy technician. (a) An emergency courtesy license may be issued to
1395	practice as a [IF THE BOARD DETERMINES THAT AN EMERGENCY EXISTS REQUIRING THE PROVISION
1396	OF LICENSED COVERAGE IN A PHARMACY THAT IS TEMPORARILY WITHOUT THE SERVICES OF A
1397	PHARMACIST DUE TO DEATH, ILLNESS, OR OTHER EMERGENCY CIRCUMSTANCES, THE BOARD MAY
1398	ISSUE AN EMERGENCY] pharmacist, pharmacy intern, or pharmacy technician in an urgent situation
1399	as determined by the board. The board will issue a military courtesy license to an active duty
1400	military member or spouse of an active duty military member. An applicant for an emergency
1401	courtesy license or military courtesy license must [PERMIT TO AN APPLICANT WHO]
1402	(1) submit [SUBMITS] a completed application on a form provided by the department
1403	<u>and</u>
1404	(A) if applying as a spouse of an active duty military member, the
1405	applicant must also submit form 08-4850;
1406	(B) if applying as an active duty military member, the applicant must
1407	also submit form 08-4633;

1408	(2) <u>pay</u> [PAYS] the <u>courtesy license</u> [EMERGENCY PERMIT] fee required in 12 AAC
1409	02.310;
1410	(3) submit documentation showing [SUBMITS VERIFICATION ON A FORM PROVIDED
1411	BY THE DEPARTMENT THAT] the applicant is currently licensed in another licensing jurisdiction and
1412	the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted
1413	except for failure to apply for renewal or failure to obtain the required continuing education
1414	requirements;
1415	(4) repealed 10/31/2019; and
1416	(5) <u>must</u> [HAS] not <u>have</u> been convicted of a felony or another crime that affects the
1417	applicant's ability to practice pharmacy competently and safely.
1418	(b) An emergency permit under (a) of this section is nonrenewable, and is valid for 90 days or
1419	until the emergency circumstances no longer exist, whichever is shorter.
1420	(c) Repealed 11/19/2020.
1421	(d) Repealed / / [IN AN URGENT SITUATION, THE BOARD MAY ISSUE AN
1422	EMERGENCY COURTESY LICENSE TO PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR
1423	PHARMACY TECHNICIAN TO AN APPLICANT WHO MEETS THE REQUIREMENTS OF THIS SECTION. THE
1424	BOARD MAY RESTRICT THE LICENSE TO ONLY THOSE SERVICES REQUIRED TO RESPOND TO THE
1425	URGENT SITUATION. THE LICENSEE MAY NOT PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR
1426	PHARMACY TECHNICIAN OUTSIDE THE SCOPE OF THE LIMITED PURPOSE FOR WHICH THE
1427	EMERGENCY COURTESY LICENSE IS ISSUED].
1428	(e) Repealed / / [AN APPLICANT FOR AN EMERGENCY COURTESY LICENSE
1429	UNDER THIS SECTION MUST SUBMIT TO THE DEPARTMENT A COMPLETED APPLICATION ON A FORM

1430	PROVIDED BY THE DEPARTMENT. A COMPLETE APPLICATION INCLUDES THE APPLICABLE
1431	APPLICATION AND LICENSING FEES ESTABLISHED IN 12 AAC 02.105].
1432	(f) An emergency courtesy license issued under this section is valid for the period specified by
1433	the board and may not exceed 120 consecutive days. An emergency courtesy license may be renewed
1434	for one additional period specified by the board, not to exceed 120 consecutive days.
1435	(g) Repealed / / [THE BOARD WILL NOT ISSUE, AND AN EMERGENCY
1436	COURTESY LICENSE HOLDER MAY NOT USE, AN EMERGENCY COURTESY LICENSE AS A SUBSTITUTE
1437	FOR A TEMPORARY LICENSE OR OTHER LICENSE REQUIRED UNDER AS 08.80].
1438	(h) While practicing under an emergency courtesy license or military courtesy license issued
1439	under this section, the holder of the [EMERGENCY COURTESY] license must comply with the
1440	standards of practice set out in AS 08.80 and this chapter.
1441	(i) The board may refuse to issue an emergency courtesy or military courtesy license for the
1442	same reasons that it may deny, suspend, or revoke a license under AS 08.80.261.
1443	(j) A military courtesy license to active duty military personnel or spouse of military
1444	personnel under this section will be issued for a period of 180 days and may be renewed for one
1445	additional period specified by the board, not to exceed 180 days.
1446	(k) For an applicant applying for licensure under this section as a pharmacy technician, the
1447	board will accept as substantially equivalent any training completed while in the United States
1448	armed forces to work as a pharmacy technician or any technician license issued by another
1449	jurisdiction.
1450	(1) In this section, "urgent situation" means a health crisis requiring an increased availability of
1451	pharmacists, pharmacy interns, [.] or pharmacy technicians, (Fff. 1/16/98, Register 145; am

1452	1/17/2007, Register 181; am 8/12/2007, Register 183; am 10/31/2019, Register 232; am 11/19/2020,			
1453	Register 236; am/, Register)			
1454	Authority: AS 08.80.005 AS 08.01.063 AS 08.80.155 AS 08.01.062 AS 08.80.030			
1455	Agenda Item 10 Return to Statutes Time: 4:12 p.m.			
1456	W7.: to 1			
1457 1458	White bagging Dr. Sababan neitomated she would tough been with the AVDh A on notantial draft language but			
1458	Dr. Schaber reiterated she would touch base with the AKPhA on potential draft language, but inquired whether there was an interim action needed to determine whether this topic falls under			
1460	1			
1461	the board's purview to regulate. Ms. Carrillo stated that she believes it falls under title 21 but can request DOL guidance, to which the board supported.			
1462	request DOL guidance, to which the board supported.			
1463	TASK 28			
1464	Ms. Carrillo will review AKPhA's model language on white bagging from Dr. Schaber and will			
1465	submit a request for DOL guidance as to whether it falls under title 21 with the Division of			
1466	Insurance or if there are any components that fall under AS 08.80.			
1467				
1468	Agenda Item 11 Public Comment #4 Time: 4:15 p.m.			
1469				
1470	Michael Coons:			
1471	We Alaska have major problems: a divide that is being caused by politics and people like Dr.			
1472	Fauci, the CDC, and the NIH, and mandates from the President and far-left states. The attempts			
1473	to deny our civil liberties of our choice is our medical care. The medical community cannot come			
1474	together to work with each other. The Hippocratic oath is do no harm, but by not working			
1475	together, this is doing harm. Having doctors search for pharmacies that will fill prescriptions			
1476	creates and adds frustration. Having pharmacies declining prescriptions also adds to the amount of			
1477	time it takes to get medications into the hands of patients to treat COVID-19. Getting pharmacies			
1478 1479	to work with doctors will lessen the divide.			
1480	Representative Kurka:			
1481	There are a large number of pharmacists who are not filling prescriptions of ivermectin for			
1482	treatment. Are there pharmacists not doing this? I'm hearing from doctors and the community			
1483	that pharmacists are feeling threatened that if they dispense ivermectin, that their licensure is being			
1484	threatened. Who is doing the threatening and where is that coming from? Who is liable? Rep.			
1485	Kurka also inquired whether amendments to the PREP Act included changes to dispensing			
1486	ivermectin and recommended the board provide more links for both sides of the argument. Rep.			
1487	Kurka concluded his comment by reiterating that ivermectin is an approved medication and has			
1488	won the Nobel Prize.			

Dr. Ruffridge stated that both the prescriber and dispenser are equally liable but that a thorough				
response will be provided in writing. Dr. Ruffridge added he would look at the PREP Act and				
respond accordingly.				
I'm calling as a concerned citizen. I was able to read through some of the slides. I'm concerne				
around the policy that if a prescriber issues a prescription for ivermectin, the pharmacist is not				
obligated to fill it. By m	aking this policy, it is	creating a gap between a	patient and their provider	
D D (C'1)	C 1	1, 1	1 11 1	
Dr. Ruffridge stated it is a fact sheet, not a policy, but something the board will continue to				
discuss and send to oth	er licensing boards and	d DHSS for their though	nts on.	
TI A CITY OO				
Dr. Ruffridge will provide written responses to Representative McCarty, Representative Kurka,				
and Representative Mc	Cabe's comments relat	ing to pharmacist disper	ising of ivermectin.	
TIA OTZ AO				
Ms. Carrillo will send Dr. Ruffridge's written comments to the representatives to the division's				
legislative liaison.				
T' A C IZ 21				
	. 1	- 41 NT 1 1-	C C 1 1 1	
Ms. Carrillo Will add the	e board's fee analysis to	o the November agenda	for further discussion.	
Aganda Itam 12	Adionen		Time: 4:20 n m	
Agenda Hem 12	Aujourn		Time: 4:30 p.m.	
Dr. Puffridge thenked t	the board for their par	ticination and reminded	them of the uncoming	
quarterly infecting screet	iuleu 101 November.			
Laura Carrillo, Executiv	ze Administrator	Date		
Laura Carrino, Executiv	C Manimistrator	Date		
Iustin Ruffridge, Chair		Date		
	response will be provided respond accordingly. Gordon DeVries: I'm calling as a concern around the policy that is obligated to fill it. By me Dr. Ruffridge stated it is discuss and send to othe TASK 29 Dr. Ruffridge will provide and Representative McCordinary McCordina	response will be provided in writing. Dr. Ruffrespond accordingly. Gordon DeVries: I'm calling as a concerned citizen. I was able to around the policy that if a prescriber issues a pobligated to fill it. By making this policy, it is concerned citizen. I was able to around the policy that if a prescriber issues a pobligated to fill it. By making this policy, it is concerned citizen. Dr. Ruffridge stated it is a fact sheet, not a positive discuss and send to other licensing boards and the send to other licensing boards and Representative McCabe's comments related to the comments related to the comments are lated. TASK 30 Ms. Carrillo will send Dr. Ruffridge's written degislative liaison. TASK 31 Ms. Carrillo will add the board's fee analysis to the comments and the comments are lated. Agenda Item 12 Adjourn Dr. Ruffridge thanked the board for their part quarterly meeting scheduled for November. Laura Carrillo, Executive Administrator	response will be provided in writing. Dr. Ruffridge added he would lor respond accordingly. Gordon DeVries: Pm calling as a concerned citizen. I was able to read through some of around the policy that if a prescriber issues a prescription for ivermec obligated to fill it. By making this policy, it is creating a gap between a Dr. Ruffridge stated it is a fact sheet, not a policy, but something the discuss and send to other licensing boards and DHSS for their thought TASK 29 Dr. Ruffridge will provide written responses to Representative McCar and Representative McCabe's comments relating to pharmacist disper TASK 30 Ms. Carrillo will send Dr. Ruffridge's written comments to the represelegislative liaison. TASK 31 Ms. Carrillo will add the board's fee analysis to the November agenda Agenda Item 12 Adjourn Dr. Ruffridge thanked the board for their participation and reminded quarterly meeting scheduled for November. Laura Carrillo, Executive Administrator Date	